

-7-

REMARKS

Claims 1-28 and 36-40 are currently pending in the application. Claims 29-35 have been canceled without prejudice or disclaimer due to a restriction requirement, and claims 1 and 36 have been amended. The amendments to claims 1 and 36 are to clarify the language that both layers include a flexibility modifying agent, and the amendments were not made in view of any art. Applicants respectfully assert that no new matter has been added and request reconsideration of the claims currently pending in the application.

Claims 1-3, 6-9, 21, 27, 36, and 38 are rejected under 35 U.S.C. §102 (e) as being anticipated by Atala (U.S. Patent No. 6,368,859). Applicants respectfully traverse the rejections.

Claim 1 relates to a composite matrix having first and second layers, each layer having a flexibility modifying agent, the first layer having at least about 5 dry weight percent flexibility modifying agent and a second layer having at least about 5 dry weight percent less flexibility modifying agent than the first layer. Applicants also note that it is incorrect that elastin is identified as the only appropriate flexibility modifying agent. See, for example, page 10, lines 7-8, page 19, lines 11-12 and page 23, lines 8-18 of the application, and the claims.

Atala does not teach or disclose a matrix having a first layer and a second layer where each layer has a flexibility modifying agent. Atala discloses an artificial sling using one or more cultured cell populations on a biocompatible structure. (Col. 6, lines 20-21). The sling can be constructed from layers of collagen or collagen secreting cells that produce collagen. (Col. 6, lines 21-31). An elastin polylayer, formed from layers of elastin secreting cells, can be chimerically interfaced with the collagen layer. (Col. 6, lines 52-64).

There is no disclosure in Atala of the collagen polylayer containing any flexible modifying agent. The collagen polylayer only contains collagen, and the elastin

-8-

polylayer only contains elastin.

Applicants respectfully submit that Atala does not teach every element of claim 1, and therefore fails to anticipate claim 1. Specifically, Atala does not disclose a composite matrix having first and second layers, each layer having a flexibility modifying agent. Rather, Atala discloses an artificial sling having one layer (the collagen or collagen secreting cell layer) without a flexibility modifying agent and another layer with elastin. Therefore, Atala does not anticipate claim 1.

Claim 36 relates to a method of forming a composite matrix, the first layer comprising at least 25 weight percent collagen and a flexibility modifying agent and the second layer comprising at least a 5 dry weight percent difference of the flexibility modifying agent than the first layer. For the reasons stated with respect to independent claim 1, Atala does not disclose a collagen or collagen secreting cell layer having a flexibility agent as defined in the present invention. Therefore, Atala does not anticipate independent claim 36.

Applicants respectfully request withdrawal of the rejection of claims 1-3, 6-9, 21, 27, 36, and 38 under 35 U.S.C. §102 (e) as being anticipated by Atala.

In paragraph 5 on page 6 of the Office Action, claims 1-28 and 36-40 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Bell, et al. (U.S. Patent No. 5,891,558), Delmotte (U.S. Publication No. 2002/0131933 A1), Gregory (U.S. Patent No. 6,372,228), and Li, et al. (U.S. Patent No. 6,391,333) taken as a whole. Applicants respectfully traverse the rejections.

As an initial matter, Applicant is confused by the Examiner's analysis in finding claims 1-28 and 36-40 obvious. First, the Examiner cites Bell et al. as a reference in alleging that the pending claims are obvious. The Examiner provides no explanation or argument in the Office Action as to why Bell et al. is cited. Applicants are left to refer to the previous Office Action mailed on April 1, 2004 and are guessing that the Examiner cited Bell et al. to allege that matrices can be in multiple layers and in multiple forms.

-9-

Second, the Examiner repeatedly cites Atala in making the obviousness rejection. Yet, Atala is not cited as one of the combination of references to allege that claims 1-28 and 36-40 are obvious.

Claim 1 relates to a composite matrix having first and second layers, each layer having a flexibility modifying agent, the first layer having at least about 5 dry weight percent flexibility modifying agent and a second layer having at least about 5 dry weight percent less flexibility modifying agent than the first layer. Applicants have defined the present invention as having a correlation between the weight percents of flexibility modifying agent in the first and second layers. Applicants also again note that it is incorrectly stated that elastin is identified as the only appropriate flexibility modifying agent in the Office Action.

None of the references cited by the Examiner disclose a correlation of a flexibility modifying agent between the layers of the disclosed substances. The Examiner alleges that Li et al. discloses a double layer oriented biopolymeric membrane where each layer is composed of reconstituted collagen. The Examiner also alleges that other biopolymeric materials may be included in the membrane such as elastin and glycosaminoglycans. The Examiner admitted that Li et al. does not disclose the correlation of the flexibility modifying agent between the first and second layers as defined in claim 1, but alleged that it was within the skill of the practitioner to make various changes to the amounts of the components based upon the usage of the membrane.

Applicants respectfully disagree with the Examiner's characterization of Li et al. Li et al. discloses a sheet membrane where the biopolymeric fibers are generally oriented in a single general direction. (Col. 1, lines 34-38). Li et al. discloses a two layered membrane can be formed where the fibers are oriented in different directions, thereby affecting the properties of the bi-layered membrane. (Col. 6, lines 8-13). Li et al. also states generally that the membranes can include elastin and glycosaminoglycan. (Col. 3, lines 24-30).

-10-

However, there is no teaching by Li et al. of modifying the concentrations of a flexibility modifying agent such as elastin. Rather, the multi-layered membrane's physical properties are modified by changing the orientation of the fibers of the layers. See generally Cols. 7-10 where all of the headings refer to an oriented membrane.

There is no disclosure in Li et al. of a composite matrix having first and second layers with different compositions of the flexibility modifying agent. Rather, Li et al. discloses a method of producing a membrane having generally oriented fibers. The membrane is cut and the oriented fibers are layered on top of each other to produce a membrane of desired physical properties. Therefore, Li et al. does not make claim 1 obvious by itself or in combination with the other cited references.

The Examiner then alleged that the Delmotte patent application discloses a biopolymer membrane similar to those claimed in that the multiple layers are contemplated and each layer comprises the biomaterials claimed, as disclosed on page 2 at paragraph 0014. The Examiner then alleged that the only difference between the disclosure of Delmotte and the claims is the explicit reference to a composite matrix where one layer differs in elastin content by at least 5% over another.

Applicant respectfully disagrees with the Examiner's characterization of the Delmotte application. Specifically, paragraph 0014 on page 2 does not disclose the layers as claimed in claim 1. Paragraph 14 discloses a list of biomaterials that can be combined with fibrin or fibrinogen, and thrombin. There is no disclosure of the weight percent of the second biomaterial that is included in the membrane, including a flexibility modifying agent as defined in the present application. Nor is there any disclosure that a second layer of the membrane has a lesser amount of the second biomaterial including a flexibility modifying agent as defined in the present invention. Therefore, the Delmotte application by itself or in combination with the other cited references does not make claim 1 obvious as the Delmotte application by itself or in combination with the other references does not disclose each and every element of claim 1.

-11-

The Examiner alleged that Gregory disclosed that elastin based matrices are known to be used as graft materials. The Examiner also alleged that the matrices can be compressed to other matrices or each other by using heat or fibrin glues and may contain cells and/or drugs appropriate to the use and the area to be treated.

Applicants respectfully disagree with the Examiner that Gregory by itself or in combination with the other cited references makes claim 1 obvious. Gregory does not disclose a composite matrix having two layers with flexibility modifying agents as defined in claim 1. Rather Gregory discloses production of the elastin or tropoelastin based membranes with molds where the molds are used to control the thickness of the membrane. (Col. 5, lines 26-29).

Gregory does not disclose the first layer having at least about 5 dry weight percent flexibility modifying agent and a second layer having at least about 5 dry weight percent less flexibility modifying agent than the first layer. Therefore, Gregory does not make claim 1 obvious by itself or in combination with the other cited references.

The Examiner then cited Bell et al. without providing reasons for inclusion in the obviousness rejection of claim 1 in the October 14, 2004 Office Action. Based upon the previous Office Action, Applicants can only guess that Bell et al. was cited for allegedly disclosing matrices can be in multiple layers and multiple forms.

However, Li et al., Delmotte and Gregory all disclose multi-layered membranes. Therefore, it is not apparent why Bell et al. was cited. However, it should be noted that Bell et al. does not disclose a matrix having two layers, where each layer has a flexibility modifying agent in the concentrations defined in claim 1. Therefore, Bell et al. either by itself or in combination with the other references does not make claim 1 obvious.

The Examiner also cited Atala by implication in making the obviousness rejection. However, Atala does not disclose the concentrations of flexibility modifying agent between the layers as defined in claim 1, as discussed above.

None of the cited references disclose a first layer having at least about 5 dry weight percent flexibility modifying agent and a second layer having at least 5 dry

-12-

weight percent less flexibility modifying agent than the first layer. Therefore, the Examiner has not met the prima facie burden for alleging obviousness.

The Examiner refers to statements in the references that state without specificity that the compositions can be changed. Based upon these broad statements, the Examiner alleges that claim 1 is obvious. However, none of the cited references discuss a correlation in the concentration of a flexibility modifying agent between the first and second layers, much less the importance of the correlation. The Examiner is using the claimed invention as a roadmap to allege that the claimed invention is obvious. This hindsight reconstruction is improper and the Examiner should withdraw the obviousness rejection.

The Examiner also rejected claim 36 as being obvious over the four cited references for the same reasons as stated with respect to claim 1. Applicants respectfully disagree that claim 36 is made obvious by the cited references.

Claim 36 defines a method of forming a composite matrix comprising fastening a first layer with a second layer, the first layer comprising at least about 25 weight percent collagen and a flexibility modifying agent and the second layer comprising a flexibility modifying agent having at least a 5 dry weight percent difference from the first layer. Claim 36 defines the present invention as a method of fastening a first layer having a selected range of collagen and a flexibility modifying agent and a second layer having a flexibility modifying agent in a defined weight percent correlation with respect to the weight percent of the flexibility modifying agent in the first layer.

None of the prior art references disclose the weight percent correlation of the flexibility modifying agent between the layers as claimed in claim 36. Applicants reincorporate arguments made with respect to the obviousness rejection of claim 1. Based upon the fact that none of the references disclose the correlation of the weight percent of the flexibility modifying agent between the layers, claim 36 is not made obvious by the cited references.

Applicants respectfully request withdrawal of the rejection of claims 1-28 and 36-

-13-

40 are rejected under 35 U.S.C. § 103(a) as being anticipated over Bell, et al., Delmotte, Gregory, and Li, et al. taken as a whole.

In view of the amendments and reasons provided above, it is believed that all pending claims are in condition for allowance. Applicant respectfully requests favorable reconsideration and early allowance of all pending claims.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicant's attorney of record, Hallie A. Finucane at (612) 334-3222.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

WESTMAN, CHAMPLIN & KELLY, P.A.

By: Hallie A. Finucane

Hallie A. Finucane, Reg. No. 33,172
Suite 1600 - International Centre
900 Second Avenue South
Minneapolis, Minnesota 55402-3319
Phone: (612) 334-3222 Fax: (612) 339-3312

HAF:lms